MAR 4 - 2005

K040202

Salter Labs CPAP High Flow Cannula System

510(k) Summary

Official Contact	Duane Kazal Director Regulatory Affairs and Quality Assurance Salter Labs, Inc. 100 West Sycamore Road Arvin, California 93203
Classification Reference	21 CFR 868.5905
Product Code	BZD – Non-Continuous ventilator
Common or Usual Name	CPAP System
Proprietary Name	Salter Labs has not determined a proprietary name at the time of this filing
Predicate Device(s)	InnoMed NasalAire™ CPAP Cannula (K number unknown) Respironics REMstar CPAP System (K012263) Respironics Virtuoso LX Smart CPAP System (K993433)
Reason for Submission	Initial Introduction into Interstate Commerce

Substantial Equivalence

The Salter Labs CPAP High Flow Cannula System is substantially equivalent to other currently available CPAP systems on the market, including the InnoMed NasalAire™ CPAP Cannula and Respironics models noted in this 510(k) Summary for the following reasons:

- Same intended use.
- Same operating principle.
- Similar technology.
- Similar manufacturing processes.

The primary difference in the Salter CPAP System is the use of a specially-designed large-bore CPAP Cannula, which is used to deliver high volume flow from a compressor to the patient's nares. No CPAP or Nasal Mask is used or intended for use. The resulting high airflow results in a measured pharyngeal pressurization of up to 12 cmH_2O and the creation of a mildly-turbulent environment within the pharyngeal airway that prevents flaccid tissue from sticking to other throat tissues.

Extensive laboratory and clinical testing was done to compare performance of the Salter Labs CPAP System to a predicate device, and was found to be very effective in treating OSA. This device is not intended for use in the treatment of Acute or Central OSA patients.

The Salter Labs CPAP System is composed of three component parts:

1) Compressor Assembly: Is a stand-alone molded enclosure that contains a high-output compressor assembly, a heater and a humidifier. The device was designed and tested to meet all requirements of the following consensus safety standards:
   - EN 60601-1: "Medical electrical equipment. Part 1: General Requirements for safety."
   - EN 60601-1-2: "Medical electrical equipment: Part 1: General Requirements for safety – 2. Collateral standard, Electromagnetic compatibility."
   - UL 2601-1: "Standard for Safety for Medical Electrical Equipment, Part 1, General Requirements for Safety."
   - IEC 529:1989: "Degrees of Protection provided by enclosures (Code IP)"
   - ISO 8185:1997 "Humidifiers for medical use – General requirements."
2) Tubing Assembly: Is an insulated connector tube ranging up to 7 feet that connects the Compressor Assembly to the CPAP Cannula.
3) CPAP Cannula: Is a specially-designed cannula with an internal bore diameter of not less than 0.130 inches. The configuration and materials used in this cannula are identical to those of other Salter Labs Oxygen Cannulas. The cannula nares are naturally positioned in close proximity to the patient's nares and the CPAP System supplies 60 lpm to the patient.

The airflow exiting the Salter Labs CPAP Cannula is heated and humidified in order to prevent drying of the patient's nasal and throat tissues. The velocity and volume of air is sufficient to pressurize the pharyngeal airway to pressures from 4 cmH_20 up to 12 cmH_2O, creating enough pressure to prevent the collapse of flaccid throat tissue. In addition, the air is supplied normally, as it would be in breathing. The result is that as the patient breathes in and out, there is a mild turbulence within the airway that also prevents the closure of flaccid tissues. Together, these actions have been demonstrated to be very effective in laboratory and clinical comparative product testing.

In summary, the device described in this submission is substantially equivalent to the predicate devices noted.

The Salter Labs device complies with the applicable standards referenced in the Guidance for FDA Reviewers and Industry "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," May 1998.

Intended Use

The Salter Labs High Volume CPAP Cannula System delivers positive airway pressure therapy and is intended for use in treating obstructive sleep apnea (OSA) in spontaneously breathing adult patients within a homecare and hospital environment.

Device Description

The Salter Labs High Volume CPAP Cannula System is a microprocessor-controlled, compressor-based system that generates positive airway pressures from 4 cmH_2O up to 12 cmH_2O. The device is intended for use with a Salter Labs connector hose that is used to connect the device to the patient interface: the Salter Labs High Volume CPAP Cannula. The device is designed to provide heated and moist air to the patient through the cannula system, rather than using a nasal or CPAP Mask. Based upon laboratory and clinical use, it has been determined by the patients using this configuration that it offered improved patient comfort and resulted in a restful nights sleep for those studied. It is anticipated that over time, this configuration will improve the degree of patient compliance compared to many of the existing systems on the market due exclusively to its improved comfort.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 - 2005

Mr. Duane Kazal
Director, Regulatory Affairs/Quality Assurance
Salter Labs, Incorporated
100 West Sycamore Road
Arvin, California 93203-2300

Re: K040202
Trade/Device Name: Salter Labs High Volume CPAP Cannula System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: December 29, 2004
Received: January 4, 2005

Dear Mr. Kazal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.1 Indications for Use

510(k) Number (if known): _____

Device Name: Salter Labs High Volume CPAP Cannula System

Indications for Use:

The Salter Labs High Volume CPAP Cannula System is intended for use in treating obstructive sleep apnea (OSA) in spontaneously breathing adult patients within a homecare and hospital environment.

Prescription Use **XX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular, General Hospital
Infection Control, Dental Devices

510(k) Number K034702

(Posted November 13, 2003)